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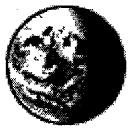

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09/12/2006 02:26 PM

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cc: Skip Matthews <mtc@mchsi.com>, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <rdenison@environmentaldefense.org>

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Subject: Environmental Defense comments on C.I. Pigment Red 49 (Barium)

(Submitted via Internet 9/12/06 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Cpma@cpma.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **C.I. Pigment Red 49 (Barium).**

The Color Pigments Manufacturers Association, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a test plan and robust summaries for C.I. Pigment Red 49 (Barium), CAS# 1103-38-4. According to this submission, C.I. Pigment 49 is used to provide color to printing inks, paints and plastics. A list of synonyms for C. I. Pigment 49 is not provided in this submission. However, it is mentioned in the text that it is also known as D & C Red 10. While it is not mentioned in the text or the list of uses of this chemical, the designation "D & C" indicates that this chemical may also be used as a pigment in drugs and cosmetics. Thus, it appears that human exposure to C.I. Pigment Red 49 may result from direct use and/or actual consumption, in addition to those exposures resulting from its use in consumer products. Its use in consumer products may also result in release into the environment in considerable quantities as a result of the production, transport, disposal and degradation of products in which it is used. Such possible sources of release and exposure should be, but were not, mentioned in this submission.

Our review of this submission indicates that C.I. Pigment 49 has been the subject of very little study. Virtually all of the data discussed were developed for a structurally related pigment, C.I. Pigment 53, also known as 53:1and D & C Pigment No. 9. The matrix of SIDS elements and associated data or estimates provided on page 3 indicates studies are available to address all the SIDS elements required under HPV, but does not indicate that these data are drawn almost entirely from the surrogate chemical, C.I. Pigment 53. The use of surrogate data should be clearly identified in this matrix. Examination of the chemical structures of these chemicals indicates that C. I. Pigments 49 and 53 share similarities; however, 49 contains a sulfated naphthalene moiety in the position where 53 has a chlorinated and sulfated toluene moiety. Thus, there are also some very significant structural differences in these two chemicals. These differences, which are not sufficiently addressed in the submission, suggest that 53 may not be a suitable surrogate for 49. We ultimately defer to EPA as to the acceptability of using this surrogate as a source of data for C.I. Pigment 49. If the EPA does not allow the use of this data as surrogate for C.I. Pigment 49, this obviously cannot be considered an acceptable submission.

It should also be noted that, unlike most other chemicals reviewed under the HPV Challenge, pigments such as C.I. Pigment 49 are usually not pure chemicals. They are named and used based on the colors they produce rather than the purity of the commercial product. Some marketed pigments are less than 50% pure. This submission does not mention the purity of C.I. Pigment 49, but it is probable that the commercial product contains a considerable number of chemicals in addition to the named compound. In most cases, these "other chemicals" are primarily reaction products, variations on the described chemical structure, salts, etc. Thus, the toxicity of a pigment may be as much or more dependent upon one or more of these "other chemicals" as the parent compound. Therefore, in determining the acceptability of surrogate data, EPA should request information on the purity of both C.I. Pigment 49 and 53, as well as a list of primary contaminants in each, their approximate quantities in the finished products, so that consideration can be given to the possible toxicity of the whole product.

Other comments:

1. The abbreviation "PEC" should be defined the first time it is used.
2. The various studies described in the test plan give the reference for the work as "a reputable journal" or as "a surrogate substance". The actual references should be provided.
3. The surrogate chemical is variously referred to as C.I Pigment Red 53, C.I. Pigment 53:1 and D & C Red 9. We assume these are the same or very similar chemicals. Whether or not this is the case should be made clear.

4. Though carcinogenicity is not a required SIDS element under the HPV Challenge, some comfort is provided by the data that indicate C.I. Pigment 49 induced no carcinogenicity or toxicity in a chronic study. We would have a great deal more confidence in this study, however, if some detail regarding the design and conduct of this study were provided in the test plan or robust summary, as called for under the HPV Challenge even for non-SIDS endpoints.
5. A robust summary of the chronic study of C.I. Pigment 53 described in some detail in the test plan needs to be provided.
6. No data are provided to address the SIDS element for Developmental Toxicity. The only information addressing this element is a note referring the reader to the "30 month toxicity study below". The description of that study provides minimal description of the results other than to say that D & C Red No. 10 was not toxic or carcinogenic. The study is quite old, was not conducted under GLP, and the description contains no description of even minimal experimental design, e.g., number of doses, dose level(s), etc. There is no mention of any examination of developmental toxicity in this study. Without data from and more information on this study and its acceptability, we don not consider this SIDS element to have been addressed.

In summary, the acceptability of this submission hinges on EPA's decision regarding the acceptability of data developed for C. I. Pigment 53 as a surrogate for that required for C.I. Pigment 49. The EPA should also request and carefully review the list of chemicals present in the products marketed as C.I. Pigments 49 and 53. And finally, this submission contains no information to address the SIDS element for developmental toxicity, without which it is not complete.

Thank you for this opportunity to comment.

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